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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/960,389 | 09/24/2001 | Mark Ashby | 034298-120 | 7856 |

7590 05/07/2003

Robert E. Krebs, Esq.
THELEN REID & PRIEST LLP
PO BOX 640640
SAN JOSE, CA 95164-0640

EXAMINER

BAXTER, JESSICA R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3731 | |

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|------------------|---|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/960,389 | ASHBY ET AL. | |
| | Examiner | Art Unit | |
| | Jessica R Baxter | 3731 | |
| <i>-- Th MAILING DATE of this communication app ars on th cov rsh t with the correspondence address --</i> | | | |
| Period for Reply | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. | | | |
| <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | |
| Status | | | |
| 1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>06 February 2003</u> . | | | |
| 2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final. | | | |
| 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | |
| Disposition of Claims | | | |
| 4) <input checked="" type="checkbox"/> Claim(s) <u>1-10 and 24</u> is/are pending in the application. | | | |
| 4a) Of the above claim(s) _____ is/are withdrawn from consideration. | | | |
| 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. | | | |
| 6) <input checked="" type="checkbox"/> Claim(s) <u>1-10 and 24</u> is/are rejected. | | | |
| 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. | | | |
| 8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement. | | | |
| Application Papers | | | |
| 9) <input type="checkbox"/> The specification is objected to by the Examiner. | | | |
| 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | |
| 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. | | | |
| 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner. | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | |
| 13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | |
| 14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received. | | | |
| 15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | |
| Attachment(s) | | | |
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ | |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) | |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | | 6) <input type="checkbox"/> Other: _____ | |

DETAILED ACTION***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/28746 to Burney et al.

Burney discloses a system comprising a catheter with a closed distal end (tip 30) and a side port (lateral opening 24) adjacent the distal end and an adaptor (needle hub 17) connected to the catheter having a tapered lumen with a large diameter proximal end and a small diameter distal end, wherein the small diameter distal end is connected to the catheter, and wherein the adaptor is removable from the catheter (page 16 lines 20-25).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/28746 to Burney et al. (Burney) in view of U.S. Patent No 5,775,333 to Burbank et al.

Burney discloses the claimed invention except for the biopsy cannula having a tissue puncturing distal end and a side port. Burbank teaches two different embodiments of a biopsy

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device: with a biopsy cannula (FIG. 14A and 14C) and without a biopsy cannula (FIGS. 6A and 6B). The biopsy device without a cannula is similar in structure to the biopsy device disclosed by Burney : a catheter having a closed distal end (FIGS. 6A and 6B end point 45) and a side port (port 46) adjacent the distal end. Burbank than teaches that a biopsy cannula may be provided on the outside of the device as an alternative mechanism for collecting a biopsy sample (FIG. 14A-14C). Burbank teaches that this biopsy cannula is provided in order to contain the sample within the catheter while the catheter is being withdrawn (Column 18 line 45-Column 19 line 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Burney with a biopsy cannula, as taught by Burbank, in order to contain the sample within the catheter as it is being moved outside of the body.

Regarding claims 4 and 5, Burney discloses first and second indexing members (Page 19 lines 20-28).

5. Claims 7-10 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/28746 to Burney et al. U.S. Patent No. 5,325,587 to Nabai et al.

Burney discloses the claimed invention except for the plegget of absorbable sponge material loaded in the adaptor. Burney discloses that his device may be used to obtain a tissue sample and deliver a composition that includes the use of radiopaque substances (page 23 lines 8-28 and page 26 lines 3-15). Nabai teaches that a sponge is delivered in order to promote healing without the necessity of suturing (Column 3 lines 11-18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Burney with a sponge in order to promote healing in the biopsy location without the need for sutures.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following references are cited to further show the state of the art with respect to biopsy devices and applicators:

| | |
|---|---|
| U.S. Patent No. 4,881,551 to Taylor | U.S. Patent No. 6,056,700 to Burney et al. |
| U.S. Patent No. 5,304,140 to Kugo et al. | U.S. Patent No. 6,162,203 to Haaga |
| U.S. Patent No. 5,358,474 to Kaldany | U.S. Patent No. 6,220,248 to Voegele et al. |
| U.S. Patent No. 5,562,613 to Kaldany | U.S. Patent No. 6,283,951 to Flaherty et al. |
| U.S. Patent No. 6,045,570 to Epstein et al. | U.S. Patent No. 6,356,782 to Sirimanne et al. |

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

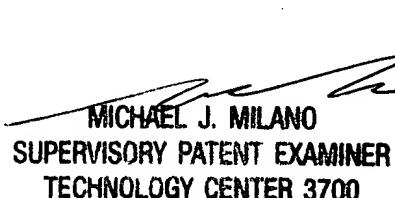
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731


jrb

May 4, 2003


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700